

best conserves the resources of the PTO. There is no undue burden on the Examiner as examination of each of the claims would require consideration of the same art. Groups II-IV do not fall under separate classifications.

Groups I & II

The Examiner asserts that Group I, drawn to SPE-A mutants and Group II, drawn to vaccines, are related as combination and subcombination. The Examiner further asserts that “the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not have the added limitation of having to induce a protective immunity against the effects of SPE-A.”

First, Applicants note that the claimed vaccine would constitute the combination and the claimed SPE-A mutants would most properly be considered the subcombination, contrary to the Examiner’s assertion.

Applicants submit that the restriction is improper because the Examiner has failed to state sufficient reasoning. MPEP § 806.05(c) states “in order to establish that combination and subcombination inventions are distinct, two-way distinctness must be demonstrated.” The Examiner’s conclusory assertion that the subcombination (which Examiner erroneously identified as the vaccine) has a separate utility does not satisfy this requirement.

Further, Applicants direct the Examiner to §806.05(c) II of the MPEP that states if there is no evidence that the specific combination is patentable without the details of the specific subcombination, restriction should not be required. Applicants submit that although a component of the claimed vaccine is one or more SPE-A mutants, the construction and use of the vaccine requires knowledge of the details of the SPE-A mutants, as they are an essential component.

Group I and Groups III & IV and Group II and Groups III & IV

The Examiner asserts that Group I, drawn to SPE-A mutants and Groups III and IV, drawn to methods of protecting an animal from the effects of SPE-A and methods of reducing symptoms associated with toxic shock, respectively, are related as product and process of use.

The Examiner also asserts that Group II, drawn to SPE-A vaccines, is also related to Groups III and IV as product and process of use. The Examiner asserts that SPE-A mutants “can be for antibody purification.” Applicant assumes that the Examiner is referring to the use of SPE-A mutants in the production of antibodies for passive immunity transfer. However, in the context of the invention, this is not the most valuable use of the invention, and indeed is not claimed in the present application. By the Examiner’s reasoning, if complicated machinery could be used as landfill, claims drawn to the process of using it could be restricted.

Applicant maintains that there is no undue burden in examining Groups I, II, III and IV. Groups II, III and IV are in the same class. The most efficient use of the resources of the PTO would be to examine the claims as submitted.

Groups III & IV

The Examiner asserts that Group III, drawn to methods of protecting animals from at least one biological activity of wild-type SPE-A and Group IV, drawn to methods of reducing symptoms associated with toxic shock “are separate and distinct as they are drawn to differing methods having different steps and leading to differing results.”

Again, Applicant maintains that the Examiner has failed to meet his burden of providing specific reasoning. MPEP § 816 states that “the particular reasons relied upon by the examiner for holding that the inventions as claimed are either independent or distinct should be concisely stated. A mere statement of conclusion is inadequate.” The Examiner just concluded that claims of Group III and Group IV “are separate and distinct as they are drawn to differing methods having different steps and leading to differing results,” without providing any reasoning. Further, inspection of the claims shows that both of the methods include, i.e., administering the same vaccine to an animal.

Applicant further asserts there is no undue burden in examining the Groups together, as they are in the same class and examination would require review of the same art.

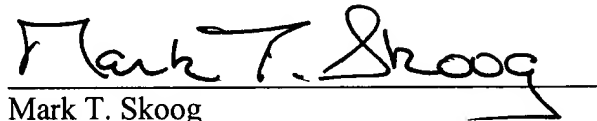
Conclusion

For the foregoing reasons, Applicants elect Group I with traverse. Applicants submit that the present Restriction Requirement is improper and withdrawal of the Restriction is therefore earnestly solicited.

Respectfully submitted,

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